SECTION 11
510(k) Summary

11.1. **Sponsor:** Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 Ease Middlefield Road
Mountain View, California 94043

11.2. **Contact Person:** Shelly Pearce
Title: Regulatory Affairs Specialist
Telephone: (650) 694 5988
Fax: (650) 694 5580

JUL 10 2012

11.3. **Submission Date:** May 7, 2012

11.4. **Device Name:** V5Ms Transesophageal Transducer (K052021)

used for

ACUSON Antares Diagnostic Ultrasound System (K063803),
ACUSON Cypress Diagnostic Ultrasound System (K052331),
ACUSON S1000/S2000 Diagnostic Ultrasound System (K112596),
ACUSON SC2000 Diagnostic Ultrasound System (K113179),
ACUSON Sequoia Diagnostic Ultrasound System (K063085),
ACUSON X300 Diagnostic Ultrasound System (K063803)

11.5. **Common Name:** Diagnostic Ultrasound Transducer

11.6. **Classification:**
Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

	FR Number	Product Code
Diagnostic Ultrasound Transducer	892.1570	90-ITX

A. Legally Marketed Predicate Devices

The Siemens V5Ms Transesophageal Transducer is Phased Array Transducers for Transesophageal Echocardiolgraphy, and is substantially equivalent to our current product, the Siemens V5Ms Transesophageal Transducer(K052021) for ACUSON Antares Diagnostic Ultrasound System (K063803), ACUSON Cypress Diagnostic Ultrasound System (K052331), ACUSON S1000/S2000 Diagnostic Ultrasound System (K112596), ACUSON SC2000 Diagnostic Ultrasound System (K113179), ACUSON Sequoia Diagnostic Ultrasound System (K063085), and ACUSON X300 Diagnostic Ultrasound System (K063803)

B. Device Description:

The V5Ms Transesophageal Transducer consists of a gastroscope control housing where nosepiece articulation and transducer rotation are controlled. A flexible transesophageal guide tube with a nosepiece containing the acoustic array extends from one end of the control housing and the system cable/connector extends from the other end. The acoustic array has 64 elements and rotates 180 degrees to provide imaging planes from transverse view to inverse transverse view. Rotation is powered by a motor in the control housing and is controlled by the operator using a switch button on the control housing for clockwise and counterclockwise rotation. Nosepiece articulation is achieved by manipulating a vertebrae section adjacent to the nosepiece through a series of control wires attached to knobs on the control housing. The nosepiece can be

articulated in both the anterior/posterior and left/right directions.

C. Intended Use

V5Ms trans-esophageal echocardiograph (TEE) ultrasound transducer is intended primarily for cardiology applications.

a. ACUSON Antares Ultrasound System

The Acuson Antares ultrasound imaging system is intended for the following applications: Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

b. ACUSON CV70 Cardiovascular System

The CV70 ultrasound imaging system is intended for the following applications: Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac. Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Gephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

c. ACUSON Cypress Ultrasound System

The Cypress platform is intended for use in the following applications:
General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (cardiac), Pediatrics, Neonatal Cephalic, Cardiac (adult, pediatric), Trans-esophageal, Peripheral Vessel, Intra-luminal and Intra-cardiac applications, and intended uses as defined in the FDA guidance document.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes

d. ACUSON S1000/S2000 Ultrasound System

The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal(conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the

American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging."

e. ACUSON SC2000 Ultrasound System

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during neurological intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

f. ACUSON Sequoia Ultrasound System

The Siemens ACUSON Sequoia ultrasound imaging system is intended for the following applications:
General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid and penis), Neonatal/Adult Cephalic, Cardiac (adult, pediatric, and neonatal), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-sceletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

g. ACUSON X300 Ultrasound System

The Siemens ACUSON X300 ultrasound imaging system is intended for the following applications:
General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
The system also provides measurement of anatomical structures and analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

Performance data is not required for this modification as there is no change to software or hardware.

F. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The product modification is for patient contact materials only. There have been no changes to software or hardware. Nonclinical tests contained in this submission include biocompatibility testing per ISO10993-1 (cytotoxicity, sensitization, irritation).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 10 2012

Re: K121807
Trade/Device Name: V5Ms Transesophageal Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: June 19, 2012
Received: June 20, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the V5Ms Transesophageal Transducer, as described in your premarket notification:

Transducer Model Number

V5Ms Transesophageal Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may

publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): k121807

Device Name: V5Ms Transesophageal Transducer

Indications For Use:

V5Ms trans-esophageal echocardiograph (TEE) ultrasound transducer is intended primarily for cardiology applications.

Acuson Antares Ultrasound System

The Acuson Antares ultrasound imaging system is intended for the following applications:
Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

ACUSON CV70 Cardiovascular System

The CV70 ultrasound imaging system is intended for the following applications:
Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac. Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Gephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

ACUSON Cypress Ultrasound System

The Cypress platform is intended for use in the following applications:
General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (cardiac), Pediatrics, Neonatal Cephalic, Cardiac (adult, pediatric), Trans-esophageal, Peripheral Vessel, Intra-luminal and Intra-cardiac applications, and intended uses as defined in the FDA guidance document.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes

ACUSON S1000/S2000 Ultrasound System

The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal(conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging."

Acuson SC2000 Ultrasound System

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to

acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during neurological intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

ACUSON Sequoia Ultrasound System

The Siemens ACUSON Sequoia ultrasound imaging system is intended for the following applications:
General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid and penis), Neonatal/Adult Cephalic, Cardiac (adult, pediatric, and neonatal), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-sceletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

ACUSON X300 Ultrasound System

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial,

OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices

510(k) K121807

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **V5Ms** Multiplane TEE Transducer for use with **ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 4
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K063138, K063803; E = added under Appendix E

Additional Comments:

Note 4 Tissue Equalization Technology

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k) K121807

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **V5Ms** Phased Sector Array TEE Transducer for use with; **ACUSON CV70 Cardiovascular System**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 2,3
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K032111, K050240; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k) K121807

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **V5Ms** Phased Sector Array TEE Transducer for use with; **ACUSON Cypress ultrasound system**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 1)		P	P	P	P	P	P			Note 3
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P			Note 3,4
Transesophageal		P	P	P	P	P	P			Note 3,4
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K052331; E = added under Appendix E

Additional Comments:

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 Contrast agent imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k) K121607

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5Ms** Multiplane TEE Transducer for user with **ACUSON S1000/S2000 Diagnostic Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P	P	P	P	P	P		BMDC	Note 4
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K063803, K072786, K081148, K082142, K090334, K093812, K111674, K112596

Additional Comments:

Note 4 Tissue Equalization Technology

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k) K121807

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5M** TEE for use with **ACUSON SC2000**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k) K121807

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5M TEE** for use with ACUSON Sequoia Diagnostic Ultrasound System

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K063085, #K052410, #K052021, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k) K121807

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5Ms** TEE Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1l& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	SmallOrgan (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K090276, and K093531

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging
Note 8 SieClear multi-view spatial compounding
Note 9 Tissue Equalization Technology
Note 10 Intracardiac imaging
Note 11 Dynamic TCE

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510(k) K121807

Page 11 of ___